REPORT DOCUMENTATION PAGE	Form Approved OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	7 MAY 97	

4. TITLE AND SUBTITLE
A CRITICAL REVIEW OF THE 1996 PRESIDENT'S MANDATE PATHOGEN REDUCTION PLAN FOR MEAT AND POULTRY

5. FUNDING NUMBERS

6. AUTHOR(S)
DANNY JOE GLOVER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

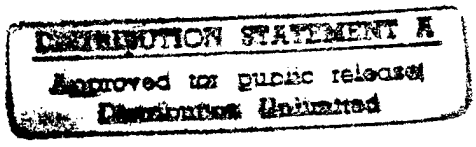
8. PERFORMING ORGANIZATION REPORT NUMBER
97-032

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
DEPARTMENT OF THE AIR FORCE
AFIT/CI
2950 P STREET
WRIGHT-PATTERSON AFB OH 45433-7765

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION AVAILABILITY STATEMENT



12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

19970512 137

14. SUBJECT TERMS	15. NUMBER OF PAGES
	42
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT

A CRITICAL REVIEW OF THE 1996 PRESIDENT'S MANDATED PATHOGEN REDUCTION PLAN FOR MEAT AND POULTRY

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A CRITICAL REVIEW OF THE 1996 PRESIDENT'S MANDATED PATHOGEN REDUCTION PLAN FOR MEAT AND POULTRY

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THESIS

Presented to the Faculty of The University of Texas

Health Science Center at Houston

School of Public Health

in Partial Fulfillment

of the Requirements

for the Degree of

MASTER OF PUBLIC HEALTH

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON
SCHOOL OF PUBLIC HEALTH
Houston, Texas
May 1997

ACKNOWLEDGMENTS

I am indebted to my many friends in the United States Air Force Public Health Service, the Food and Drug Administration, the United States Department of Agriculture, the Centers for Disease Control and Prevention, and the United States Army who have worked with me over the past few years on numerous food safety and policy development issues. I gratefully acknowledge the entire staff at the UTHSC School of Public Health - San Antonio for their inspiration, encouragement, and assistance. Finally, appreciation is extended to my principle advisor, educational counselor, mentor, and friend, Dr. Alfonso H. Holguin.

Thesis submitted to the MPH Committee on Mar 10, 1997.

A CRITICAL REVIEW OF THE 1996 PRESIDENT'S MANDATED PATHOGEN REDUCTION PLAN FOR MEAT AND POULTRY

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The University of Texas
Health Science Center at Houston
School of Public Health. 1997

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In spite of diligent inspections of meat by the United States Department of Agriculture's Food Safety and Inspection Service, an illness transmitted predominately by contaminated food, hemorrhagic colitis caused by *Escherichia coli* 0157:H7, poses a serious health threat to the general public. Reported outbreaks from *E. coli* 0157:H7 are increasing each year, and the most common source of infection for humans has traditionally been undercooked beef.

The number of outbreaks reported to the Centers for Disease Control and Prevention has continued to increase from 1982-95. The epidemiologic evidence indicates the risk factors for *E. coli* 0157:H7 are changing, and disease is occurring in environments that were previously considered safe. Media coverage has made this infection widely known among the general public, yet the steps in preventing this illness are not being addressed. A small but

vocal group of lobbyists has successfully influenced the Executive branch of the government to mandate a politically responsive new policy. This Presidential mandate was announced on July 6, 1996, but in spite of the millions of dollars in implementation costs, it does not completely address the problem of protecting the public's health from *E. coli* 0157:H7.

This thesis examines the policy of meat inspection prior to the Presidential mandate, providing a summary of the responsibilities and procedures for ensuring a wholesome meat supply. A summary of the newly announced Presidential mandate, "Pathogen Reduction and Hazard Analysis and Critical Control Points Systems" is thoroughly described, including the reason for the recent policy change.

The specific illness that prompted this policy change, hemorrhagic colitis caused by *E. coli* 0157:H7, is thoroughly described and the changing epidemiologic characteristics are presented to illustrate how the new Presidential mandate will not adequately nor accurately prevent this illness.

A thorough review of the epidemiology and risk factors associated with hemorrhagic colitis caused by *E. coli* 0157:H7 are presented and discussed. The ineffectiveness of the mandate and the inability of the policy change to protect the health of the public are evaluated, and a recommendation to implement the recently revised FDA Food Code is presented.

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INTRODUCTION

On July 6, 1996 the President of the United States, Bill Clinton, made the following announcement in his weekly RADIO ADDRESS TO THE NATION:

10:06 A.M. EDT. THE PRESIDENT: *(QUOTE)*

Good morning. This holiday weekend we celebrate America's birthday and the values that hold us together as a community and a country. It's a time for family and fun, for games and fireworks and backyard barbecues.

Tonight, smoke will curl over homes on nearly every block as millions of families gather around the grill for the most American of meals: hamburgers and hot-dogs and barbecued chicken.

Today I want to talk to you about the steps we're taking to make sure the food we cook in backyard barbecues is safe and wholesome. Our families have every right to expect the food they serve their children is safe. They have every right to expect the world's most bountiful food supply will also be the world's safest. And, in fact, our food is very safe.

Nearly a century ago, after muckrakers exposed dirty conditions in meat-packing plants, we made a national commitment to protect the public from unsafe food. It was one of the first ways we came together to meet the challenges of that new industrial age.

Last year, we put in place new safety precautions for seafood. And in recent years, we've learned that we all must continue to be vigilant on meat and poultry safety, and we learned it the hard way. For, every year, scores of Americans still die and tens of thousands become sick from eating meat or poultry that is contaminated with harmful bacteria.

We all remember how, in 1993, tragedy struck hundreds of families in the western United States. Undercooked hamburgers served in a fast food restaurant were contaminated with a deadly strain of E. coli bacteria. Five hundred people became ill and four children died.

The parents of many of the E. coli victims turned their grief into a determination to help others. Some of them are here with me today. In the face of this unspeakable tragedy, they had one insistent question: How could this have happened? I asked that question too, and I asked my administration: What can we do to prevent it from happening again?

Now, sometimes food makes us sick because it's undercooked. But sometimes, families have been exposed to illnesses because some meat and poultry shipped to our supermarket shelves contain invisible and deadly bacteria. The reason was shocking and simple: For all our technological advances, the way we inspect meat and poultry had not changed in 90 years. Even though we know that killers such as salmonella can only be seen with a microscope, inspectors were still checking on meat and poultry by look, touch,

smell. We relied on an overworked cadre of government inspectors, rather than working with the industry and challenging it to keep food safe.

Under the direction of Vice President Gore and Secretary Glickman, the United States Department of Agriculture has worked with industry, scientists, farmers, parents and consumers to completely revamp our meat and poultry inspection system, to revolutionize the way our nation protects food safety.

This morning, I want to announce the major changes that the U.S. Department of Agriculture will take to keep food safe and to protect our children from deadly bacteria.

First, we're challenging every meat-packing plant in America to do scientific tests or take other safety precautions at every step of production. Each company must design and put in place its own tough plan. We're not imposing a detailed list of dos and don'ts. We're working with industry as partners, challenging them to find ways to make our meat the safest it can be. Each plant will be held accountable for meeting high standards at every step of the process.

Secondly, we're insisting that every slaughterhouse begin to conduct rigorous scientific tests to make sure the meat is not contaminated with deadly strains of E. coli and salmonella bacteria.

Third, companies will have to improve their sanitation procedures. All too often, food is contaminated because simple sanitary rules are not followed.

All these changes will be phased in over the coming months to make sure they are done right. These new meat and poultry contamination safeguards will be the strongest ever. They are flexible and they do challenge the private sector to take responsibility. They also use the most up-to-date science to track down invisible threats. They protect the public without tangling business in red tape.

Parents should know that when they serve a chicken dinner they're not putting their children at risk. Parents should know that when a teenager borrows the car to get a fast food hamburger, the hamburger should be the least of their worries. Our new food safety initiative will give families the security to know that the food they eat is as safe as it can be.

To be sure, parents will also still have to take responsibility. There is no way to make food entirely free from risk, nature simply won't let us. So everyone should follow warning labels, be careful how you handle raw meat and poultry, and make sure it's well cooked before you serve it to your family. These days families have enough to worry about. They shouldn't have to fear the food they eat is unsafe. With the tough steps we're taking today, America's parents should be able to breathe a little easier.

Have a safe and happy Fourth of July weekend. *(UNQUOTE).*

END 10:11 A.M. EDT

The President's announcement introduced a program that is officially known as "The Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems." As the President stated, this plan involves changes to the inspection procedures that have been in place for decades, and is a significant departure from the previous policy. The probable outcome from implementing this policy change must be considered. This thesis will review the policy of meat inspection prior to the Presential mandate and summarize the new program. It will summarize the clinical and epidemiologic aspects of hemorrhagic colitis caused by *E. coli* 0157:H7, the disease that prompted the policy change. Using the changing epidemiologic picture and known risk factors associated with *E. coli* 0157:H7, an analysis and synthesis of the reported outbreaks will be presented. Finally, this thesis will demonstrate the ineffectiveness of microbiological testing of raw meat as a means of improving food safety to the consumer.

A REVIEW OF THE PREVIOUS POLICY REQUIREMENTS

The Food Safety and Inspection Service (FSIS), a public health agency in the U.S. Department of Agriculture, protects consumers by ensuring that meat and poultry products are safe, wholesome, and accurately labeled. Current Food Safety and Inspection Service regulatory requirements and inspection procedures are designed to ensure that meat and poultry products are safe, wholesome, and accurately labeled. There are more than 7,400

FSIS inspectors who regulate approximately 6,200 slaughter and processing facilities. Inspectors check animals before and after slaughter, visually examining over 6 billion poultry carcasses and 125 million livestock carcasses, including beef, pork, and lamb, each year. They prevent diseased animals from entering the food supply and examine freshly slaughtered carcasses for visible defects that can affect safety and quality. FSIS also inspects products during processing, handling, and packaging to ensure that they are safe and truthfully labeled.

FSIS sets standards for a range of activities associated with the production of meat and poultry products. For instance, the Agency evaluates and sets standards for food ingredients, additives, and compounds used to prepare and package meat and poultry products. All plant facilities and equipment must adhere to FSIS standards and be approved before they can be used. The Agency sets labeling standards and approves labels for meat and poultry products. Standards are also set for certain slaughter and processing activities, such as plant sanitation and thermal processing.

FSIS regulates meat and poultry products that account for a third of all consumer spending for food, with an annual retail value of $120 billion. FSIS regulates all raw beef, pork, lamb, chicken, and turkey, as well as approximately 250,000 different processed meat and poultry products, including hams, sausage, soups, stews, pizzas, and frozen dinners (any product that contains 2% or more cooked poultry or 3% or more raw meat). Consumers purchase these products packaged with 500,000 different USDA approved labels.

All animals presented for slaughter must pass an antemortem evaluation by an FSIS inspector, e.g. they must be ambulatory, alert, and appear healthy and normal. Any animal(s)

that displays signs of an underlying illness or abnormality is separated out for a more complete physical examination including temperature determination. Diseased animals are removed from the human food supply prior to slaughter.

After animals are determined to be healthy and normal, and are approved for slaughter, the FSIS inspectors enforce facility sanitation and proper carcass handling procedures throughout the slaughtering process. This is a multi-step process and requires thorough and continuous inspector oversight throughout all stages. It begins with the humane stunning of the animal, usually by employing a captive bolt device which delivers a sharp sudden blow to the cranium, rendering the animal unconscious. The unconscious animal is then shackled with a chain attached to a hind leg, and lifted off the floor. Animals are killed by exsanguination while they are unconscious. The bleeding procedure is accomplished by severing the large vessels at the base of the throat (superior vena cava and carotid artery) causing the blood to pour out of the body. The head is removed and the front legs are severed at the knee. This is a critically important step and is performed early in the slaughter process because removing the mouth, nose, ears, eyes, and hooves eliminates a major source of potential contamination. The carcass is then advanced on an overhead chain in what will be a series of "assembly line" procedures.

The hide removal begins at the hock joint of the hind legs. The skin is incised from the medial surface of one hind leg across the midline to the opposite leg. The distal portion of the hind legs, including the hooves, are removed at the hock joint. The skin incision is continued along the ventral midline towards the head. The urinary bladder is removed intact and the

rectum is incised and tied off with string to prevent spillage of fecal contents on the carcass. The breastbone is split, exposing the thoracic organs, and the anterior end of the esophagus is tied off with string to prevent contamination from gastric reflux. The entire gastrointestinal system is removed intact with both the anterior and posterior ends tied off. Following the removal of the gastrointestinal system, the heart, lungs, and trachea are removed simultaneously and intact.

The final step in carcass production is the hide removal. The skin is loosened from the front legs and neck and is secured to a chain. The legs are secured with a stationary chain and the skin is pulled away from the carcass in a manner which effectively peels it off, "inside out". This procedure is much like stripping off your shirt without pulling it from the sleeves, resulting in turning it "wrongside out". This technique allows removal of the hide without the hair touching the surface of the carcass.

Following hide removal, the carcass is split into right and left sides, washed with warm water to remove any blood and to blanch the fat to it whitest color, wrapped snugly in a shroud, and placed in refrigerated storage for thorough chilling. After the sides have thoroughly chilled, they are ready for further processing into primals, subprimals, retail cuts, or they may enter the distribution chain as an entire side of beef.

The technique for slaughtering cattle has been developed because it has been proven to provide the consumer with the cleanest carcass at the lowest cost. The FSIS inspectors are responsible to ensure that workers adhere to sanitary methods throughout the slaughtering process, and that sides of beef are refrigerated promptly after slaughter. FSIS has traditionally

carried out carcass-by-carcass inspections in slaughter plants to remove from the food supply diseased animals, or diseased portions of an animal, that may not have been detectable at antemortem.

In spite of the technique currently employed for slaughtering cattle, the carcasses will always contain some bacterial contaminants. Operating a slaughtering plant as if it were a surgery suite is the only way to preclude bacterial contamination, and that is economically inconceivable. The most common source of contamination comes from the hide, hair, and hooves of the live animals as they enter the slaughterhouse, and from the gastrointestinal tract of the animals. The microbial contaminants from the animals are spread throughout the slaughterhouse by the movement of the animals along the processing line, by workers, clothing of workers, utensils, equipment, air, and water. The only variable at this point is the degree of contamination and this depends on the degree of sanitation practiced during the slaughter-dressing procedures (1).

SUMMARY OF THE NEW POLICY REQUIREMENTS

On February 3, 1995, the Food Safety and Inspection Service (FSIS) published a proposal on Pathogen Reduction and Hazard Analysis and Critical Control Points (HACCP) that would:

1. Mandate HACCP for all meat producing plants
2. Set targets for pathogen reduction
3. Require daily microbial testing to determine compliance with the targets

4. Require three initiatives -

    a. standard operating procedures for sanitation

    b. antimicrobial treatments of carcasses

    c. carcass cooling standards

FSIS conducted a thorough and interactive rulemaking process on the proposal by soliciting extensive public comment and encouraging dialogue between FSIS and interested parties on the many policy and technical issues involved in the proposal.

During the comment period, which was extended twice, FSIS held seven information briefings, three scientific and technical conferences, a two-day public hearing, six issue-focused public meetings, a Federal-State conference, and a Food Safety Forum chaired by Secretary of Agriculture Dan Glickman. In addition, FSIS received approximately 7,500 written comments on the proposal.

FSIS carefully evaluated the written comments and other input received from the various public events and formulated a final rule.

The Final Rule (39)

The Food Safety and Inspection Service (FSIS) established new requirements for all meat plants designed to improve food safety and modernize USDA's meat inspection system.

All slaughter and processing plants will be required to adopt the system of process controls to prevent food safety hazards known as Hazard Analysis and Critical Control Points (HACCP). To verify that HACCP systems are effective in reducing contamination with

harmful bacteria, FSIS is setting pathogen reduction performance standards for *Salmonella* that slaughter plants, and plants that produce raw ground meat will have to meet. In addition, slaughter plants will be required to conduct microbial testing for generic *E. coli* to verify that their process control systems are working as intended to prevent fecal contamination. FSIS is also requiring plants to adopt and follow written Standard Operating Procedures for sanitation to reduce the likelihood that harmful bacteria will contaminate the finished product.

FSIS expects this combination of HACCP-based process control, microbial testing, pathogen reduction performance standards, and sanitation standard operating procedures to significantly reduce the contamination of meat with harmful bacteria and reduce the risk of foodborne illness.

USDA believes this new food safety system will also enable modernization of its inspection program by focusing attention on the most significant food safety hazards and on ensuring all plants have systems in place that are effectively preventing food safety problems. Since the final rule is several hundred pages in length, the new requirements of the final rule are summarized.

Hazard Analysis and Critical Control Points (HACCP) Systems

FSIS is requiring all federally inspected meat plants to adopt HACCP systems to ensure that they have in place science-based process controls to prevent and reduce the significant food safety hazards that may arise in their particular processes and products. The HACCP approach is a system of process control that is widely recognized by scientific

authorities and international organizations and is used extensively in the food industry to produce products in compliance with health and safety requirements. HACCP also provides a framework for better targeting FSIS inspection on the most significant food safety hazards and controls and more efficiently using inspection resources.

Implementation of HACCP will clarify the responsibility of industry and FSIS to produce safe meat products. FSIS's role is to set appropriate food safety standards and maintain vigorous inspection oversight to ensure that those standards are met.

Plants will be required to develop HACCP plans based on the seven principles articulated by the National Advisory Committee on Microbiological Criteria for Foods:

1. Hazard Analysis - This is the beginning step and is used to identify biological, chemical, and physical hazards of significance. It includes a risk assessment to predict the likelihood of occurrence and the method of prevention/avoidance.

2. Critical Control Point Identification - This procedure is for determining the exact location within a process where a hazard exists, usually identified from flow charts. The identified hazards are critically evaluated for the purpose of avoiding or preventing them if possible. Hazards that cannot be completely avoided are prepared for through proper planning.

3. Establishment of Critical Limits - Not all critical control points pose health hazards. Usually there is a range within which a process can operate and still be safe. This safe range is the critical limit whose boundaries must not be crossed (example: potentially hazardous food items like raw meat should be kept refrigerated, but may be at room temperature for brief

periods, not to exceed a cumulative time of 4 hours. In this instance 4 hours is the critical limit for the food to be unrefrigerated.)

4. Monitoring Procedures - Monitoring is absolutely necessary to ensure the processes are operating within the critical limits, and to recognize if the safe boundary of the critical limit is crossed.

5. Corrective Actions - These actions are planned responses which are designed to bring the processes back to a safe range of operation. If deviation occurs at a critical control point and the critical limit is exceeded, the person monitoring the process must initiate the corrective action.

6. Record Keeping - This includes the preparation and maintenance of a complete written HACCP plan and includes the flow diagrams, critical control points, critical limits, monitoring procedures, and assigned responsibilities for all employees.

7. Verification - The final step is simply making sure the plan is adequate and working on a day-to-day basis. It will be the responsibility of both industry and FSIS. HACCP plans found by FSIS to be inadequate will have to be corrected, or the plant will face appropriate regulatory action.

Plants will identify and evaluate the food safety hazards that could affect the safety of their products and institute controls necessary to prevent those hazards from occurring or to keep them within acceptable limits. HACCP systems will be required to cover those critical control points that affect product safety, as opposed to those related to economic adulteration and quality. Each meat product produced must be covered by a HACCP plan. Industry will

monitor and verify the performance of the controls in their HACCP plans and maintain records of this monitoring and verification. FSIS will evaluate the HACCP plan's adequacy and successful operation as part of the inspection process. Plants will be required to validate their own HACCP plans--that is, ensure that they do what they were designed to do. FSIS will not approve HACCP plans in advance but will review them for conformance with the final HACCP regulations.

All plants must develop, adopt and implement a HACCP plan for each of their processes. FSIS believes that HACCP-based process control, combined with appropriate food safety performance standards, is the most effective means available for ensuring the safety of food, including controlling and reducing harmful bacteria on raw meat products.

FSIS is committed to implementing HACCP as rapidly as possible, taking into account the logistical effort required for such a fundamental change in industry practices and FSIS inspection strategy. FSIS has revised its proposed implementation schedule so that it is based on plant size rather than product category. Large plants with 500 or more employees will be required to have a HACCP system in place 18 months after publication of the final rule. The revised implementation schedule will ensure that 75 percent of slaughter production and 45 percent of processed products will be produced under a HACCP system within 18 months. Smaller plants, with 500 or fewer but 10 or more employees, must have a HACCP system in place 30 months after publication of the final rule. Very small establishments--those having fewer than 10 employees or annual sales of less than $2.5 million--have until 42 months after publication of the final rule to have their HACCP systems in place.

On July 25, 1996, USDA published the final rule, "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems," and officially began the sweeping reformation of the 90-year-old meat inspection system.

Pathogen Reduction and Microbial Testing

The HACCP requirement will ensure that all meat plants implement science-based process controls to prevent and reduce the significant food safety hazards that are considered reasonably likely to occur in their particular processes and products. HACCP-based process control will be combined with an objective means of verifying that meat and poultry plants are achieving acceptable levels of food safety performance, newly required microbiological monitoring for *Salmonella* and *Escherichia coli*. While the Food Safety and Inspection Service already had in place microbiological performance standards for ready-to-eat and other processed products, microbiological performance criteria or standards for raw products, with the exception of *E. coli* O157:H7 in ground beef, did not exist.

FSIS believes it is essential to the reduction of nationwide exposure to foodborne pathogens that slaughter establishments use HACCP and microbiological monitoring to control their operations to prevent fecal contamination and that all plants producing raw meat products institute process controls to reduce the prevalence of *Salmonella*. It is believed these regulations provide both an objective means to verify process control in slaughter plants with respect to fecal contamination and pathogen reduction performance standards for raw

products that are expected to reduce the nationwide exposure to *Salmonella*, an enteric pathogen reported to be the most common cause of foodborne illness.

Generic *E. Coli* Testing

FSIS is requiring meat slaughter plants to test carcasses for generic *E. coli* as an indicator of the adequacy of the plant's process control for fecal contamination. Plants will be required to conduct *E. coli* testing 6 months after publication of the final rule. FSIS inspectors will not use *E. coli* testing results as an indication of process control until 6 months after the effective date for the testing requirement. A conference is tentatively planned for approximately 9 months following publication of this rule to provide an opportunity for members of industry and others to discuss with FSIS new information based on the three months of testing that will have occurred that might justify further adjustments to the protocol.

FSIS is adopting *E. coli* verification performance criteria for each species that reflect the frequency and levels of contamination of the microorganism on such carcasses produced nationwide as determined by FSIS baseline surveys. FSIS is using the term 'criteria' because they are guidelines, not regulatory standards. FSIS will not use the test results by themselves to take any regulatory action but will consider them in conjunction with other information to evaluate whether a problem exists that requires regulatory action.

The required frequency of *E. coli* testing is based on production volume. Slaughter plants will be able to adopt alternative testing frequencies after they implement HACCP, if the alternative is equally or more effective in verifying process control for fecal contamination. FSIS intends to update the *E. coli* criteria periodically, based on future surveys and data generated by the testing, to ensure that the criteria adequately reflect an appropriate and adequate level of performance with respect to prevention and removal of fecal contamination.

The requirement for *E. coli* testing in slaughter plants will become effective 6 months after publication of the final rule. It is believed that *E. coli* test results will provide process control data that will help plants find and correct process control problems at this most fundamental phase of production. The results will also support more objective assessments by inspectors of whether plants are meeting current statutory requirements for sanitation and the prevention of adulteration. They will also play an integral role in the successful implementation of HACCP in slaughter plants.

Salmonella Testing

FSIS is adopting pathogen reduction performance standards for *Salmonella* to verify that HACCP systems in the plants are effective in reducing contamination with this pathogenic microorganism. FSIS believes that the production of raw meat with *Salmonella* prevalence below the current national level is readily achievable with available technology and production methods. *Salmonella* was selected as the target pathogen because it is reportedly the leading cause of foodborne illness among enteric pathogens, it is present at varying frequencies on all

types of raw meat products, and it can easily be tested for in a variety of products. Furthermore, improvements in process control that result in reductions in *Salmonella* are expected to result in reductions of other pathogens found in the intestines of animals.

The microbiological performance standards FSIS is adopting are part of a fundamental shift in FSIS regulatory philosophy and strategy. FSIS is shifting from an extensive reliance on command and control regulations, which generally prescribe how desired objectives are to be achieved, to a much greater reliance on performance standards, which generally express the objective but do not specify the means for achieving it. FSIS believes that its food safety and consumer protection goals can, in most cases, be achieved most effectively by establishing clear objectives in terms of performance standards, providing industry flexibility to devise the optimal means of achieving the objective, and then verifying that plants are meeting the established standard through inspection and other forms of oversight.

The Food Safety and Inspection Service believes the pathogen reduction performance standards for *Salmonella* and the *E. coli* verification performance criteria complement one another. They say that while *E. coli* testing is a good indicator of fecal contamination, it is not directly correlated with *Salmonella* contamination, which is affected by other factors as well, including the condition of incoming animals. Plants will be required to achieve a prevalence of *Salmonella* contamination that is below the baseline prevalence for each raw product as reflected in the FSIS baseline surveys. These are regulatory standards that FSIS will require the plant to meet consistently over time as a condition to maintaining inspection.

FSIS, rather than the plant, will test for *Salmonella* to ensure compliance with the standards. FSIS will conduct initial testing prior to actual enforcement of the performance standards to determine whether each plant is meeting the standard. These results will assist plants in preparing for implementation of HACCP and the pathogen reduction performance standards. FSIS will continue its testing program once the standards become effective to ensure compliance. The frequency and intensity of testing will be based on past plant performance.

Implementation will coincide with the implementation schedule for HACCP. Slaughter plants and plants producing raw ground product will be required to meet the standards at the same time the plant is required to implement HACCP. Approximately 15 months after the publication of this final rule, FSIS will convene a public conference to review available data and discuss whether they warrant refining the *Salmonella* performance standards.

Standard Operating Procedures for Sanitation

Insanitary conditions during the production of meat products increase the likelihood that pathogenic bacteria will contaminate the finished product. Poor sanitation is the most frequently observed problem in meat plants. FSIS is requiring that all meat plants adopt, maintain, and follow written Standard Operating Procedures (SOPs) for sanitation. The written sanitation SOPs must describe the specific activities plant management has determined are necessary to maintain good sanitation and prevent direct product contamination. The SOP

must specify the persons responsible for carrying out these activities. Daily records must be kept showing when procedures are accomplished and when corrective actions are taken.

Sanitation SOPs will clarify that sanitation is industry's responsibility. They will make it easier for FSIS inspectors to perform their proper role of verifying that plant management is carrying out its sanitation responsibilities and will allow FSIS to focus on the prevention and correction of direct product contamination risks.

All plants must prepare and implement plant-specific standard operating procedures (SOPs) for sanitation to ensure they are meeting their responsibility to keep their facilities and equipment clean. This requirement will become effective 6 months after publication of the final rule.

Safe Handling Beyond the Plant

The new regulatory measures address hazards within slaughter and processing plants. FSIS recognizes, however, that these measures must be part of a comprehensive food safety strategy that addresses hazards at other points in the farm-to-table chain. To that end, FSIS is broadening the scope of its food safety activities beyond slaughter and processing plants, with particular new emphasis on hazards that arise during transportation, distribution, and retail sale.

To improve food safety at the animal production and intermediate stages before the slaughter plant, FSIS has reported they are working with industry, academia, and other government agencies to develop and foster measures that can be taken on the farm and

through distribution and marketing of animals to reduce food safety hazards associated with animals presented for slaughter. FSIS does not intend to mandate production practices at this stage but instead believes that the voluntary application of food safety assurance programs based on HACCP principles can be useful in establishing risk reduction practices on the farm and during intermediate marketing stages. The Agency believes that continued public concern about foodborne pathogens and the adoption of HACCP and performance standards will increase incentives for producers to adopt food safety practices at the animal production level.

Food safety during transportation, storage and retail sale are also important links in the food safety chain. In these areas, FSIS, the Food and Drug Administration (FDA), and State and local governments share authority for oversight of food products. FSIS announced they are working together with FDA to develop standards governing the safety of foods during transportation and storage, with particular emphasis on the importance of temperature control in minimizing the growth of pathogenic microorganisms. In the retail area, claims are made that FSIS and FDA are working together with state officials to ensure the adoption of uniform, science-based standards and to foster the adoption of HACCP-type preventive approaches. State and local authorities have primary responsibility for food safety oversight of retail stores and restaurants, but FSIS and FDA, working through the Conference for Food Protection, can provide expertise and leadership to support local authorities and foster the development of sound food safety standards and practices nationwide.

Even as progress is made in reducing contamination during these stages, it will remain critical that retail food handlers and consumers follow safe food handling practices. Proper

storage, preparation, and cooking of meat products are essential to achieving the goal of reducing the risk of foodborne illness to the maximum extent possible. FSIS intends to augment its food handler education efforts by expanding its collaboration with industry, other government agencies, consumer and public interest groups, educators and the media to foster the effective delivery of food safety education and information.

Implementation Costs

FSIS estimates the four-year implementation cost of the final rule to the meat industry at $305 to $357 million, or an average of $76 to $89 million per year. Annual recurring costs following the implementation period are estimated at $99.6 to $119.8 million.

HEMORRHAGIC COLITIS SYNDROME CAUSED BY *Escherichia coli* 0157:H7

The question of when and how the *Escherichia coli* 0157:H7 strain became pathogenic has often been asked. Although there were isolations of verotoxin-producing *E. coli* organisms as early as 1977 (16), and five isolations of the *E. coli* 0157:H7 serotype prior to 1981 (18), it is believed that the 0157:H7 serotype was not a cause of disease outbreaks prior to 1982. Review of over 3,000 *E. coli* strains serotyped by the Centers for Disease Control and Prevention between 1973 and 1983 revealed no record of outbreaks of bloody diarrhea of unknown origin before 1982, suggesting that the 0157:H7 serotype is not likely to have been a frequent cause of illness in the United States prior to that time (13). Some believe the toxin producing capability was gained as a result of a mutation (42), while others

theorize this capability was passed from *Shigella dysenteriae* to *Escherichia coli* through conjugal transfer of a chromosomal segment (gene transfer) made possible by a bacteriophage vector (37). Regardless of when, how, or why *Escherichia coli* 0157:H7 emerged, it is now recognized as a significant foodborne pathogen that causes serious illness and occasional death in humans. Though it has been reported in many countries around the world, this manuscript is limited to the outbreaks reported in the United States.

Etiology and Symptoms

Escherichia coli 0157:H7 is a human pathogen that causes a gastrointestinal illness characterized by severe cramps, little or no fever, and frequent diarrhea which usually turns bloody. Diarrhea occurs as a result of inflammatory edema of the colonic mucosa, followed by erosion and hemorrhage (32). A typical illness from *Escherichia coli* 0157:H7 begins with severe abdominal cramps and nonbloody diarrhea. The stool turns bloody on the second or third day, and bloody diarrhea usually lasts 2 to 4 days. Patients have described the cramps as being comparable to childbirth pains, and the diarrhea may be all blood with little or no stool. Vomiting has been noted in about half of the patients, fever in less than a third, and when fever is present, it is not high. (12). See figure 1 for a chronological representation of the developing symptoms.

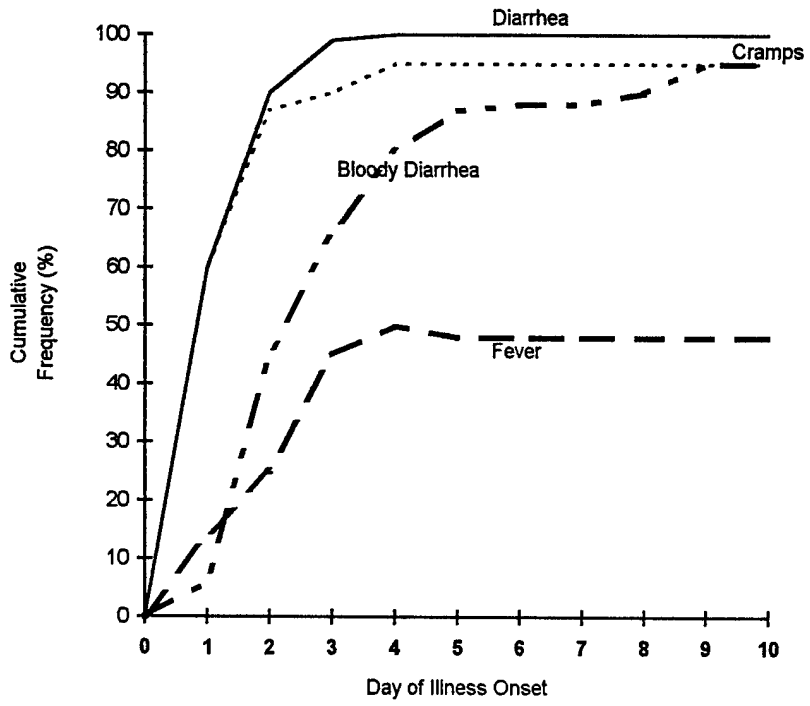

Figure 1: Cumulative Frequency of Symptoms

In some cases, the diarrhea remains nonbloody throughout the course of the illness, and those patients have reported less severe cramping. Asymptomatic infection has also been reported but is believed to be rare (3). Illness caused by *Escherichia coli* 0157:H7 usually resolves 6 to 8 days after onset. In some patients, however, the illness progresses to a more serious condition, hemolytic uremic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). These complications develop most often in the young, the elderly, and the immunocompromised (12, 14).

Infected humans shed *E.* coli 0157:H7 in the feces for an average of 17 days (range 2 to 62). Some may shed intermittently and shedding duration is unrelated to bloody versus nonbloody diarrhea (4).

Pathogenesis

Escherichia coli 0157:H7 is categorized as a Shiga-like toxin-producing *E. coli* (SLTEC) with a well recognized capability for attaching to and effacing the gut mucosa. By definition, all Shiga-like toxin-producing *E. coli* organisms produce one or more toxins. These toxins closely resemble the toxin produced by *Shigella dysenteriae* type 1, hence the name. When Konowalchuk first identified a Shiga-like toxin-produced by an *E. coli* strain in 1977, he called it a vero-toxin because of its cytotoxic effect on vero cells from the kidney of African green monkeys. Although it is confusing, the dichotomous nomenclature still exists today, with the author's preference of whether to follow the terminology of the original Konowalchuk nomenclature using 'verotoxin', or follow the terminology that describes its biochemical similarities and use 'Shiga-like toxin'.

Strains of *E. coli* 0157:H7 produce two toxins, one which is neutralized by antisera to Shiga toxin produced by *Shigella dysenteriae* type 1, and the other not. The term SLT 1 (or verotoxin 1) is used for the toxin that is neutralized and SLT 2 (or verotoxin 2) is used for the other. The role of Shiga-like toxins (SLT) in diarrheal illness is not well understood, however evidence suggests that SLT may act both locally and systemically on the gut mucosa:

1. When applied locally, SLT caused nonbloody fluid accumulation to rabbit ileal loops (15).

2. Parenteral injection of SLT in rabbits resulted in nonbloody diarrhea and lesions in the cecum resembling those of humans infected with *E. coli* 0157:H7. Parenteral injection of SLT in mice resulted in bloody diarrhea and sloughing of the mucosal surface and crypt epithelial cells (2).

Adherence to intestinal mucosal cells and the production of SLT are thought to be the major virulence properties of *E. coli* 0157:H7. The organism adheres to the mucosa of the intestine and destroys the microvilli (23). Colonic vascular damage by SLT may provide access for the toxin and other inflammatory mediators into the circulatory system, thus initiating the complication, hemolytic uremic syndrome (HUS). This theory supports the observation that patients with bloody diarrhea are more likely to develop HUS than those with nonbloody stools. Data on humans suggests that SLT 2 is a more important virulence factor than SLT 1 for progression of *E. coli* 0157:H7 infection to HUS (25).

The infectious dose of *E. coli* 0157 has not been determined, but it is believed to be low in comparison to other pathogenic foodborne bacteria. Sample cultures taken from raw ground beef that was implicated in a 1993 outbreak recovered as few as 15 organisms per gram (37). Frozen ground beef in a Canadian outbreak was found to have 100 organisms per gram (36).

Transmission

The most common source of infection for humans is through ingesting contaminated food. Among the 22 reported outbreaks that occurred between 1982 to 1992, 14 were the result of contaminated food and 8 of those 14 specifically from ground beef. In 1993, 14 of 17 outbreaks were traced to contaminated food, and 9 of the 14 to ground beef. Food is thought to be contaminated by coming in contact with feces, or fomites that are contaminated with feces, from reservoir animals. To date, the only animal found to be a reservoir is domestic cattle, and even then, the shedding of the organism is inconsistent (11, 21, 37, 41). Illness from *E. coli* 0157:H7 has been associated with consumption of meat products (especially ground beef) in most of the reported outbreaks prior to 1994, but the organism has also been a documented contaminant in other retail foods: salami, unchlorinated water (35), raw milk, apple cider, mayonnaise, venison jerky, and fruits and vegetables (13, 26, 37).

Person to person transmission by fecal-oral route has been reported (13, 29, 30, 33) and is the dominant mode of transmission in outbreaks in day care centers (13). In 1995, a large number of outbreaks reported to CDC (7 of 32) were associated with water, swimming water, or ice. Although little is known about the natural occurrence or ecology of this organism, a great deal has been learned in recent years about its role as a food and environmental contaminant and as a causative agent for illness in man.

Epidemiological Considerations

The 0157:H7 serotype is a member of the enterohemorrhagic *E. coli* group, and is considered one of the most significant emerging pathogens. It causes illness in humans by it's ability to adhere to and erode the microvilli of the intestines, and by the production of a potent toxin, commonly referred to as Shiga-like toxin (SLT), also referred to as a verotoxin. Toxins from *E. coli* strains were first identified in 1977 (16), and were called verotoxins because of their cytotoxic effect on cultured Vero cells (kidney cells from African green monkey).

E. coli 0157:H7 was first recognized as a foodborne pathogen following an investigation of two outbreaks of hemorrhagic colitis in Oregon and Michigan in 1982 (31, 32). The illness was epidemiologically linked to the ingestion of hamburgers from a fast food restaurant chain, with the *E. coli* 0157:H7 strain being isolated from the stool of about half of the patients and from the beef patties that were supplied to the Michigan restaurants. The isolates were clinically different from previously grouped *E. coli*, thus the enterohemorrhagic group was established.

Since the 1982 outbreaks, *E. coli* 0157:H7 has been associated with consumption of meat items, especially ground beef. In 1989, a waterborne outbreak occurred indicating this organism was not limited to meats, and since then, the organism has been the cause of illness in other outbreaks where the contaminated foods were concluded to be retail foods, salami, unchlorinated water (35), raw milk, apple cider, mayonnaise, venison jerky, and fruits and vegetables (13, 26, 37). These food items are thought to have been contaminated with *E. coli* 0157:H7 by cross contamination from bovine feces. It has been generally agreed that

consumption of undercooked ground beef is the highest risk factor for contracting the illness, but it is increasingly apparent that many different foods can harbor and transmit viable pathogenic *E. coli* O157:H7 organisms in a sufficient quantity to cause illness (8, 26). This expands the community at risk to all people in the United States.

Infection has been documented to occur from person to person (fecal - oral route) when personal hygiene and sanitation standards were questionable (29, 30, 33). These reports have been relatively rare, however, when compared to the number of outbreaks that have resulted from ingestion of contaminated food.

From the descriptive epidemiology of this disease, a seasonal peak of outbreaks has been observed with more occurring during the summer (13). Although there is no certain explanation for this seasonal increase, it has been theorized that it is associated with an increase in summertime cookouts of ground meat and an increased opportunity for temperature abuse of contaminated meat products (37).

Outbreaks have been observed in healthy adults, among whom it is reported that 23% of affected persons were hospitalized, 6% developed HUS or TTP, and 1 % died (5), but the disease is reported to occur most often in the young, the elderly, mentally retarded institutionalized persons, and the immunologically compromised (8, 13, 29, 30, 33). The illness is more severe in the young, the elderly, and the immunologically compromised, where it is reported up to 10% of the patients develop HUS and approximately 5% of those HUS cases die (5).

Physical/Environmental Considerations

E. coli organisms in general are very common in the environment, especially where humans and animals reside. They are part of the normal flora in the feces of both man and animals and are a common indicator organism for evidence of fecal contamination. Some animals are shedders of the *E. coli* 0157:H7 strain, even though they appear normal and healthy. It has been reported that about 5% of animals between weaning age and adult are intermittent shedders. The inconsistent shedding by animals has led investigators to believe that an antemortem test prior to slaughter would NOT be reliable at identifying positive reservoir animals. (11, 21, 41). Slaughter of animals whose intestinal tract is colonized with the 0157:H7 strain presents the possibility of contaminated carcass beef, capable of causing severe foodborne illness, being delivered to consumers, even though it may be originating from plants that are operating under the Food Safety and Inspection Service (FSIS) inspections.

The production of beef in modern slaughter facilities is designed to eliminate, or at least reduce to the lowest possible level, contamination of carcasses with fecal material. Since it is economically unfeasible to operate a slaughter facility under the same strict standards as a surgery suite, it is impossible to produce carcass beef that is totally free from contamination. Because of fecal contamination on the hooves, hair and skin of animals prior to slaughter, some fecal contamination of carcass beef is inherent in the slaughtering technique, by cross contamination from workers, equipment in the facility, and carcasses contacting each other (37).

Contamination of carcass beef is limited to the surface only unless the product has undergone additional processing such as grinding, chopping, comminuting, tenderizing, or injecting with flavoring agents (e.g. corned beef), which can introduce the pathogens deep into the interior of the meat (40). Ground or chopped products pose more of a risk for infection with *E. coli* 0157:H7 because the bacteria is distributed throughout the product and thorough cooking to a well done state is required to ensure lethality for all bacterial contaminants.

In order for beef to proceed from a slaughter facility through the distribution chain to a food serving facility, it goes through numerous processes. Many of the processes allow the potential for further contamination with, or the multiplication of pathogenic microbes. The following is not complete, but is a good generic list of most of the processes; and provides an understanding of the complexity of the beef slaughter industry:

1. Upon slaughter, the carcasses are "sided" (divided through the center of the vertebral column) into the right and left halves, and hung in a refrigerated room for 18 to 36 hours for thorough chilling.
2. Following the chilling process, they are "ribbed" (cutting part way through the carcass between the 12th and 13th rib to expose a cross section of the longissimus dorsi muscle). This procedure allows visualization of the loin muscle, aiding the USDA meat grader in assigning an accurate quality grade (Prime, Choice, Select, Standard, Commercial, Utility, Canner & Cutter).

3. Carcasses are subdivided into primal cuts (chuck, rib, shortloin, sirloin, round, etc.) for easier handling and marketing. Beef trimmings and beef from animals of substandard quality grades (Standard, Commercial, Utility, Canner & Cutter) are used for processed meats or ground beef (hamburger). The primals and the ground beef are vacuum packaged, and boxed for wholesale distribution.

4. Refrigerated (or sometimes freezer) trucks are used to transport the boxed beef to wholesalers (grocery suppliers, warehouses for corporate restaurant chains, etc.) where the meat is stored until it is delivered to the local grocery market or restaurant.

5. Grocery markets process the primal cuts into retail cuts, where they are wrapped and priced, and offered for sale to the American public. Restaurants may produce their own retail cuts, or may purchase them from a wholesaler who produces them.

Throughout the chain of events, meat is handled multiple times by workers, and is placed in and out of refrigeration numerous times (37). The extensive handling allows many opportunities for additional contamination or cross contamination, and the temperature fluctuations allow for proliferation of the bacteria that are present. It is impossible to supply raw beef at the retail level that is free of contamination, and some of the contaminants will likely be pathogenic to humans (1, 13, 26).

Behavioral Considerations

Partial cooking of beef is very common among American consumers. Eating beef with a rare center does not pose a public health threat if the beef is a "whole muscle cut" that is completely intact, and is thoroughly cooked on the outer surface. Potentially harmful pathogens that may be present will be limited to the external surface only. As long as the meat has not been penetrated with a meat fork prior to cooking, or prepared in a manner that would allow the introduction of the surface contaminants further into the internal areas of the cut, partial cooking is safe. Cooking of beef to a rare condition will provide adequate heat to the external surface of the meat to kill all the surface microbes (40).

Cuts that are other than "whole muscle", however, can never be made safe unless they are thoroughly and completely cooked throughout. Ground beef, butterfly cut filets, stuffed cuts, and tenderized or injected cuts of meat have the potential to harbor pathogenic microorganisms internally as well as on the surface, and must be cooked enough to reach a minimal internal temperature of 155° F for 15 seconds to ensure the pathogens are killed during the cooking process (18, 37). Monitoring with a cooking thermometer is not necessary; one can be sure the meat has been adequately cooked when the pink color turns gray and the juices run clear.

Another behavioral factor contributing to the public health threat is the common use of knives, cutting boards, serving platters, counter tops, and sinks, between raw meat and ready to eat foods (salad items, breads, cooked meat). Washing or wiping these pieces of equipment without adequately sanitizing leaves viable pathogens from raw meat on the

equipment.. Using the same cutting boards or countertops to prepare ready to eat salad bar items or sandwiches allows cross contamination. This dangerous behavior is one of the most common causes of foodborne illness outbreaks in food service facilities, and is also very common in the home (40).

SUMMARY AND ANALYSIS OF RECENT *E. coli* 0157:H7 OUTBREAKS

The Foodborne and Diarrheal Disease Branch of the Centers for Disease Control and Prevention maintains a national database of *E. coli* 0157:H7 investigations. From 1982-1992, the pathogenic potential of *E. coli* 0157:H7 was not well understood, and as a result many outbreaks were not recognized, investigated, nor reported. For that time period, outbreaks without a clear source or site were not included in their database. In 1993, they began tallying all outbreaks of *E. coli* 0157:H7 infections reported to state health departments, whether or not a common source was identified. Consequently, 12 of 30 (40%) of the reported outbreaks for 1994 are categorized as "Source Unknown".

Mandatory reporting of *E. coli* 0157:H7 infection is not required in all states, but reporting is improving. Soon after the recognition of this organism as a human pathogen, Washington became the first state to require reporting in 1987. By 1993, reporting was required in 18 states, and currently 32 states have a mandatory reporting procedure for *E. coli* 0157:H7. A factor that has contributed to the increased reporting of *E. coli* 0157:H7 is improved surveillance due to laboratory testing of bloody diarrhea by physicians. Screening

tests for *E. coli* 0157:H7 are now considered the standard of care for patients presenting with bloody diarrhea.

From February 1982 through December of 1995, 101 outbreaks of illness in the United States caused *by E. coli* 0157:H7 involving 2,789 persons were reported to the Centers for Disease Control and Prevention (CDC). 79 of those outbreaks involving 1,966 persons occurred during the 1993-95 time period. Reasons for the increase are best explained as a result of increased awareness of *E. coli* 0157:H7 as a pathogen, improved diagnostic methods, more frequent laboratory testing of bloody diarrhea by physicians, and increased surveillance. A close look at the likely vehicle or mode of transmission listed in the CDC reports reveals some interesting observations, indicating the epidemiology for *E. coli* 0157:H7 is changing.

Let us first analyze the data for the 1982-1992 time period. The unpublished data was obtained directly from the Foodborne and Diarrheal Disease Branch of the Centers for Disease Control and Prevention. During the first 12 years after *E. coli* 0157:H7 had been identified as a human pathogen, 22 outbreaks were reported and involved 823 persons. Table 1 summarizes the outbreaks from 1982-1992.

Table 1: Outbreaks of *E. coli* 0157:H7 Reported to CDC 1982-92						
OutBrk	**YEAR**	**DATE**	**STATE**	**SETTING**	**No. ILL**	**SOURCE / VEHICLE**
1	1982	Feb	OR	Community	26*	Ground Beef
2	1982	May	MI	Community	21*	Ground Beef
3	1984	Sep	NE	Nursing Home	34*	Ground Beef
4	1984	Sep	NC	Day Care	36	Person-to-person
5	1986	May	NC	Day Care	15	Person-to-person
6	1986	Oct	WA	Community	37*	Ground Beef Ranch Dressing
7	1987	Jun	UT	Custodial Institution	51*	Ground Beef Person-to-person
8	1988	May	WI	School	61*	Roast Beef
9	1988	Aug	MN	Day Care (9 Centers)	38	Person-to-person
10	1988	Oct	MN	School	54*	Ground Beef
11	1989	Aug	WA	Restaurant	3	Unknown
12	1989	Dec	Mo	Community	243	Water
13	1990	Jul	ND	Community	65*	Roast Beef
14	1990	Dec	MT	School	10	School lunch
15	1991	Jul	OR	Community	21	Swimming Water
16	1991	Aug	WA	Picnic	2*	Ground Beef
17	1991	Sep	MN	Fair	8*	Ground Beef
18	1991	Nov	MA	Community	23	Apple Cider
19	1992	May	NY	Unknown	5	Unknown
20	1992	Jun	NV	Day Care	57	Person-to-person
21	1992	Sep	ME	Home	4	Vegetable Person-to-person
22	1992	Dec	OR	Community	9	Raw Milk
	1982-92	**TOTAL**			**823**	
	TOTAL FROM BEEF				**359***	

In 10 of the 22 reported outbreaks, beef products were responsible for, or associated with, the outbreaks. Of the 823 persons reported as ill, 359 of the infections were the result of eating contaminated ground or undercooked beef. Over 45% of the reported outbreaks

and 43.6% of the persons who suffered an illness, were caused by ground beef or beef product. These reports led investigators to the realization that the leading risk factor during that time period was consumption of beef products (13, 37).

During 1993, the source of *E. coli* 0157:H7 involving beef or beef products accounted for 9 of the 17 reported outbreaks (52.9%) and the number of persons getting ill from consuming beef or beef products was 786 of 1000 (78.6%). Table 2 presents a summary of outbreaks for 1993, and illustrates the increase for both the percentage of outbreaks associated with beef, and the number of people getting ill from beef or beef products. This confirmed that eating undercooked ground beef was the biggest single risk factor for acquiring illness caused by *E. coli* 0157:H7.

Since 1993, a dramatic change in the epidemiologic pattern of *E. coli* 0157:H7 has been observed regarding the source of most outbreaks. Widescale publicity and media coverage of the large outbreak in the Pacific Northwest associated with the Jack-in-the-Box fast food restaurant chain resulted in heightened consumer awareness of the potential for foodborne illness from eating undercooked ground beef.

Many fast food restaurants revisited and improved their facility sanitation and foodhandling procedures. Safe handling and cooking labels were made mandatory for raw meat and poultry products sold to the public. As a result, the threat of hemorrhagic colitis from ground beef or beef products decreased.

Table 2: Outbreaks of *E. coli* 0157:H7 Reported to CDC 1993						
OutBrk	**YEAR**	**DATE**	**STATE**	**SETTING**	**No. ILL**	**SOURCE / VEHICLE**
1	1993	Jan	ID	Restaurant	13*	Ground Beef
		Jan	NV	Restaurant	58*	Ground Beef
		Jan	CA	Restaurant	32*	Ground Beef
		Jan	WA	Restaurant	629*	Ground Beef
2		Mar	OR	Restaurant	47	Mayonnaise
3		Jun	ME	Unknown	4	Unknown
4		Jun	OR	Home	6	Raw Milk
5		Jul	NC	Day Care	27	Person-to-person
6		Jul	IL	Community	8	Unknown
7		Jul	NM	Party	4	Unknown
8		Jul	MA	Community	10*	Ground Beef
9		Jul	WA	Church Picnic	16	Pea Salad
10		Jul	CA	Home	10*	Ground Beef
11		Aug	OR	Restaurant	27	Cantaloupe
12		Aug	PA	Community	3*	Ground Beef
13		Aug	WA	Restaurant	53	Salad Bar
14		Sep	CT	Club BBQ	23*	Ground Beef
15		Sep	MT	Community	8*	Ground Beef
16		Oct	WA	Restaurant	9	Unknown
17		Oct	TX	Unknown	13	Unknown
	1993	**TOTAL**			**1000**	
		TOTAL FROM BEEF			**786***	

Not only were the outbreaks associated with beef or beef products less common in 1994 and 95 (Tables 3 and 4) than they were in previous years, the number of persons getting ill from beef were far less than that observed during the period from 1982 to 1993. Only 10 of 30 outbreaks (33.3%) and 128 of 511 persons (25%) occurred in 1994 and 11 of 32 outbreaks (34.4%) involving only 98 of 455 persons (21.5%) were observed in 1995. This trend is observed in spite of the increased awareness, improved surveillance, and increased

reporting of illness outbreaks caused by this organism. This changing epidemiologic pattern illustrates that beef or beef products are less of a risk factor now than they were prior to 1994. This pattern is illustrated in Figure 2.

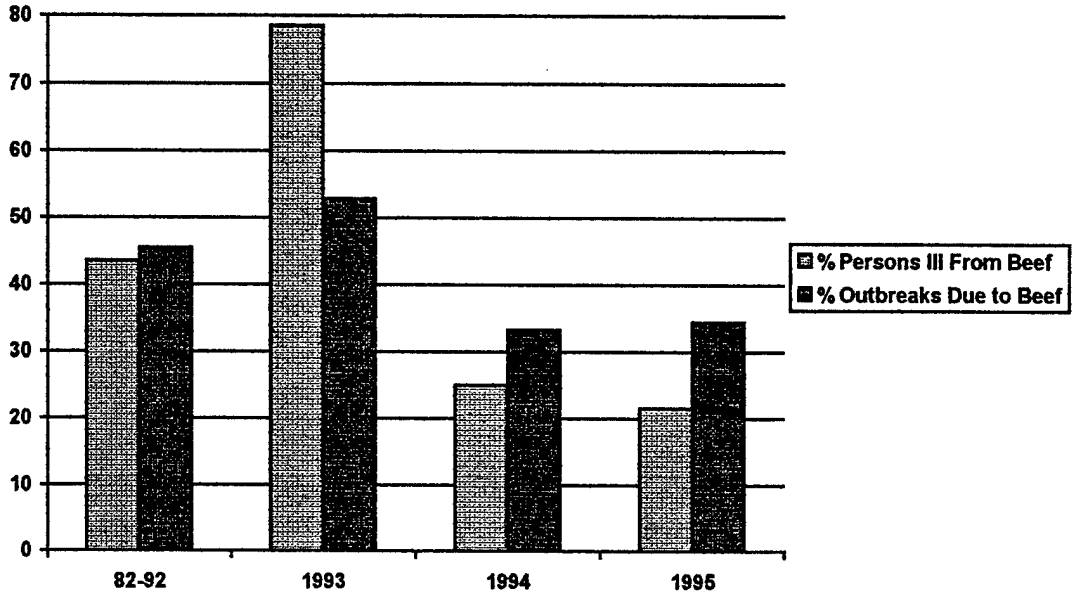

Figure 2: % Outbreaks and Persons Ill From Beef Associated *E. coli* 0157:H7

Table 3: Outbreaks of *E. coli* 0157:H7 Reported to CDC 1994						
OutBrk	**YEAR**	**DATE**	**STATE**	**SETTING**	**No. ILL**	**SOURCE / VEHICLE**
1	1994	Jan	WA	Home	11*	Ground Beef
		Jan	OR	Home	10*	Ground Beef
2		Feb	MN	Community	8*	Ground Beef
3		Apr	NE	Home/Camp	24*	Ground Beef
4		May	ND	Restaurant	33*	Ground Beef
5		May	CA	Home	9*	Ground Beef
6		May	OH	Community	10*	Coney Dog Sauce
7		Jun	NY	Home	17*	Ground Beef
8		Jun	CT	Home	21	Retail Foods
9		Jun	CT	Community	2*	Ground Beef
10		Jun	PA	Home	4*	Ground Beef
11		Jun	OH	Day Care	8	Person-to-person
12		Jul	VA	Community	7	Unknown
13		Jul	VA	Camp	20	Unknown
14		Jul	OH	Community	5	Unknown
15		Jul	WI	Day Care	43	Person-to-person
16		Jul	OK	Restaurant	4	Unknown
17		Jul	HI	Unknown	17	Unknown
18		Jul	NY	Day Camp	5	Unknown
19		Jul	MI	Day Care	13	Person-to-person
20		Jul	NJ	Homes	89	Unknown
21		Jul	NY	Community	12	Swimming Water
22		Aug	TX	Cafeteria	26	Salad Bar
23		Aug	KY	Market	6	Unknown
24		Aug	FL	Unknown	9	Unknown
25		Aug	OH	Day Care	6	Person-to-person
26		Sep	MN	College	11	Unknown
27		Sep	NY	Oktoberfest	36	Unknown
28		Oct	WA	Home	7	Apple Cider
29		Nov	WA	Home	15	Salami
		Nov	CA	Home	4	Salami
30		Nov	NM	School	20	Unknown
	1994	**TOTAL**			**511**	
		TOTAL FROM BEEF			**128***	

Table 4: Outbreaks of *E. coli* 0157:H7 Reported to CDC 1995						
OutBrk	**YEAR**	**DATE**	**STATE**	**SETTING**	**No. ILL**	**SOURCE / VEHICLE**
1	1995	Mar	OR	Day Care	4	Person-to-person
2		May	MN	Picnic	2	Ground Beef
3		May	NC	Day Care	33	Person-to-person
4		May	MN	Home	4	Ground Beef
5		Jun	SD	Camp	3*	Ground Beef
6		Jun	GA, TN	Restaurant	8*	Ground Beef
7		Jun	IL	Lake	12	Swimming Water
8		Jun	CO	Day Care	25	Person-to-person
9		Jun	WI	Lake	8	Swimming Water
10		Jul	MT	Community	74	Lettuce
11		Jul	NY	Home	12*	Ground Beef
12		Jul	NY	Camp	5	Unknown
13		Jul	CO	Camp	21*	Ground Beef
14		Jul	MN	Lake	6	Swimming Water
15		Jul	MN	Lake	2	Swimming Water
16		Jul	MN	Camp	9	Water
17		Jul	MA	Fair	8*	Ground Beef
18		Aug	ID	Lake	4	Swimming Water
19		Aug	WI	Festival	27	Ice
20		Aug	CT	Camp	24	Unknown
21		Aug	MN	Church	31*	Roast Beef
22		Sep	ME	Camp	37	Lettuce
23		Sep	ID	Restaurant	12	Lettuce
24		Sep	WA	Home	2*	Ground Beef
25		Oct	KS	Wedding	21	Punch, Fruit Salad
26		Oct	OH	Community	11	Unknown
27		Oct	NY	Home	2*	Ground Beef
28		Nov	OR	Home	11	Venison Jerky
29		Nov	VT	Home	3	Unknown
30		Nov	MN	Home	5*	Ground Beef
31		Nov	IL	Church	4	Unknown
32		Dec	CA	Prison	5	Unknown
	1995	**TOTAL**			**455**	

In 1995, 7 of 32 outbreaks were traced to water, swimming water, or ice. This represents a significant deviation from previous years when only 3 of 69 outbreaks over a 13 year period were traced to water or swimming water. Table 5 illustrates the data.

Table 5: Outbreaks of *E. coli* 0157:H7

	Outbreaks Traced to Water	Total Outbreaks Reported
1982-94	3	69
1995	7	32
TOTAL	10	101

A statistical analysis of these data was performed using the conditional Poisson binomial test to determine the probability that the increased number of outbreaks reported in 1995 occured by chance. A *p-value* of less than 0.015 was calculated, and may be viewed as very strong evidence of a changing epidemiologic pattern for this organism.

An outbreak reported in October 1994 involved apple cider and demonstrated another changing epidemiologic characteristic of the *E. coli* 0157:H7 serotype. Prior to this outbreak, it was generally agreed that *E. coli* 0157:H7 would not survive at a pH below 4.6. However, the investigators of this outbreak determined the apple cider involved was moderately acidic, with a pH of 3.1 - 3.3. Viable *E. coli* organisms of the 0157:H7 serotype were recovered from the apple cider after it had been sealed and on the shelf for 30 days. Apples that had fallen off the trees had been damaged when hitting the ground and were the apples used to

make the cider. The orchard had been used earlier in the year to graze cattle, and residue from bovine manure contaminated the ground under the apple trees. It is presumed that the damaged peeling allowed the *E. coli* 0157:H7 entry into the apples. Additionally, the apple cider was prepared for a health food store and was not pasteurized nor treated with preservatives, resulting in contaminated cider. This outbreak demonstrated a strain of *E. coli* 0157:H7 that was capable of surviving for a longer period at a much lower pH than previously believed, and is further evidence that this organism is undergoing some biochemical changes.

The CDC report "Surveillance for Foodborne Disease Outbreaks - United States, 1988-92" reviewed all outbreaks reported to the Centers for Disease Control from Janruary 1988 through December 1992 (7). This 66 page report analyzed and summarized the etiology, source, vehicle of transmission, morbidity, and mortality of foodborne disease in the U.S. for the defined period. It reported that bacterial pathogens caused the largest percentage of outbreaks (79%) and the largest number of cases (90%). Of all bacterial pathogens reported, *Salmonella enteritidis* accounted for the largest number of outbreaks, cases, and deaths.

DISCUSSION

The descriptive epidemiology confirms that illnesses caused by *E. coli* 0157:H7 and *Salmonella* are associated with a variety of sources, many of which have not been identified. The outbreaks and the number of persons getting ill from eating beef or beef products has decreased since 1993. Eating ground beef is much less of a risk factor that is was prior to

1994. A public health initiative that targets beef as the primary risk factor for illness from *E. coli* 0157:H7 or *Salmonella*, such as the mandated "Pathogen Reduction and Hazard Analysis and Critical Control Points Systems", will not provide the public with protection from the many other sources that have been associated with outbreaks. On the contrary, the Presidentially mandated plan for meat might well prove counter-productive for the consumers of beef and beef products. In recent years, many consumers have altered their cooking preferences in order to decrease the risk of acquiring hemorrhagic colitis from *E. coli* 0157:H7, and are eating beef cooked more thoroughly. With the mandate and implementation of this new pathogen reduction plan, the beef consumers are likely to develop a false sense of security about the safety of raw beef, and may revert to their prior preference of eating beef rare, including rare ground beef. As a result, we may see a resurrgence in the outbreaks of hemorrhagic colitis from *E. coli* 0157:H7 in beef instead of the decrease that has been noted since 1993.

A close reading of the radio address script that was announced by President Clinton on July 6, 1996 clearly explains the reasons for the proposed changes that have been announced for inspecting raw meat:

> [*QUOTE*] And in recent years, we've learned that we all must continue to be vigilant on meat and poultry safety, and we learned it the hard way. For, every year, scores of Americans still die and tens of thousands become sick from eating meat or poultry that is contaminated with harmful bacteria.

We all remember how, in 1993, tragedy struck hundreds of families in the western United States. **Undercooked hamburgers served in a fast food restaurant were contaminated with a deadly strain of E. coli bacteria**. Five hundred people became ill and four children died.

The **parents of many of the E. coli victims turned their grief into a determination to help others. Some of them are here with me today**. In the face of this unspeakable tragedy, they had one insistent question: How could this have happened? I asked that question too, and I asked my administration: What can we do to prevent it from happening again?

[*UNQUOTE*]

The public attention and outrage that resulted from the large outbreak of hemorrhagic colitis caused by *E. coli* 0157:H7 in the Pacific Northwest in 1993 and the CDC reports that *Salmonella* is the leading cause of foodborne illness outbreaks, cases, and deaths are the obvious reasons this mandate has been imposed.

While it is certainly noble to strive for continuous improvement in the way we do things and look for improved procedures and more economical ways to complete specific tasks, the announced "Pathogen Reduction and Hazard Analysis and Critical Control Points Systems" mandate will not accomplish that goal. In the third paragraph quoted above, the President states that food sometimes makes people sick because it is undercooked. I would argue that the only time fresh meat causes a bacterial illness in humans is when it is undercooked. While it is true that meat purchased in a supermarket may contain invisible and

deadly bacteria, they are the type of organisms that can be easily killed with proper cooking. The only foodborne illness that cannot be prevented by proper cooking is Staphylococcal intoxication, , and Staphylococcal organisms are not a commonly isolated species of bacteria on fresh meat. When Staphylococcal organisms are present, they do not compete well with other organisms and toxin production is not considered a risk in raw meat (19).

When Upton Sinclair exposed the insanitary conditions in America's major meat packing plants in his book "The Jungle", public outrage occurred. Since that era, the public has depended upon the federal government for ensuring a safe food supply. The food-producing and food-service industries have undergone many changes since the federal government first began their regulatory role for protecting the public's health through food inspection and facility sanitation inspections. The Food Safety and Inspection Service, and the Food and Drug Administration have enjoyed the reputation of ensuring the safest food supply in the world. Because of their successful track record, they have undergone relatively little change in their methods for inspecting food and facilities, compared to the many changes that have occurred in industry. Incorporation of HACCP systems and Sanitation Standard Operating Procedures (SSOPs) by industry are important factors in maintaining a safe food supply. These methods are applicable to all food production/processing procedures and can be significant factors in controlling foodborne illness outbreaks. Microbial testing of raw meat, on the other hand, will be certain to yeild positive cultures but are a meaningless finding for determining wholesomeness and food safety (1). We must accept the fact that raw meats will contain microbes, some of which are normal inhabitants of the animals gastrointestinal

tract, and are pathogenic to humans. We should focus on the factors that allow the emergence and reemergence of disease causing organisms. Dr David Satcher recently summarized some of the more significant changes that are believed to be major contributors to emerging and reemerging disease (34), including an increased risk of foodborne illness:

1. Ecological change, such as those due to agricultural or economic development or to anomalies in climate, is a major factor for disease emergence. The result is frequently a situation where people are placed in contact with a natural reservoir or host that was present, but previously unrecognized or considered insignificant as a human pathogen. This has been responsible for many disease conditions such as schistosomiasis (dams), Rift Valley fever (dams and irrigation), Hantavirus pulmonary syndrome (weather anomalies allowing increased rodent population). This is not considered a major factor for foodborne illness outbreaks but is significant for emerging diseases.

2. Human demographic changes and behavior, often caused by migration to escape war or economic conditions, are considered to be the primary factors in outbreaks of dengue fever and HIV infection (drug use). This is not considered a major factor for foodborne illness outbreaks but is significant for emerging diseases.

3. International travel and commerce provides an opportunity for rapid and widespread dissemination of diseases that were once geographically contained. Vectorborne diseases are at the top of the list for this factor, but foodborne and water

borne disease are also beneficiaries. The cholera outbreak introduced into South America (*Vibrio cholera* 0139) is the result of international travel.

4. Technology and industry, with the globalization of food supplies and changes in food processing and packaging provides ample opportunities for widespread illness. A pathogen present in some of the raw material may find its way into a larger batch of final product, such as contamination of hamburger with *E. coli* 0157:H7, and the many outbreaks of hemorrhagic colitis that have resulted.

5. Microbial adaptation and change presents a continuous threat. Microbes, like all other living things, are constantly evolving. Pathogens can acquire new genes from other non-pathogenic species in the environment, sometimes resulting in increased virulence and pathogenecity.

6. Breakdown of public health measures provide opportunities for pathogens, which are already present but are normally held in check, to respond to a breakdown in classical public health infrastructure and cause disease. Waterborne disease outbreaks, including cholera in South America and hemorrhagic colitis in Missouri are examples.

In the United States, we have experienced the factors described in # 4, 5, and 6 above. In recognizing and acknowledging these factors as constant threats to a safe food supply, we must formulate a plan that will effectively deal with the consequences of their occurrence, for these are not the type of thing that can be effectively prevented.

The final rule published by the United States Department of Agriculture states that this "Pathogen Reduction and Hazard Analysis and Critical Control Points Systems" plan will

enable USDA to modernize its inspection program by focusing on the most significant food safety hazards (pg. 12, this manuscript), but we know that food safety hazards continuously change as a result of emerging and re-emerging pathogens. In order for any plan to attain a "modernized" status, it would have to be dynamic, and capable of rapidly responding to the changing epidemiologic causes of food borne illness. The "Pathogen Reduction and Hazard Analysis and Critical Control Points Systems" is a rigid plan that is focused on two organisms, *Salmonella* and *E. coli*. The time involved for development, coordination, and planned implementation covers a 5 year time period, and can hardly be considered a dynamic and responsive program when so much time is required for the initial implementation.

The supporters of this mandate also state that FSIS and FDA are working together to develop standards governing the safety of foods during transportation and storage, with particular emphasis on the importance of temperature control in minimizing the growth of pathogenic microorganisms. The fact is the Food and Drug Administration developed and published an updated Food Code in 1993. That comprehensive document was further updated with slight revisions and republished in 1995. It addresses all aspects of food safety during transportation, storage, preparation, and serving. It is very unfortunate that to date only the USAF, the US Army Veterinary Command, and one state (Rhode Island) have adopted the FDA Food Code in its entirety, and municipalities in only 6 other states have adopted specific portions of the Code. An Executive Order requiring the food producing and food-service industries to comply with the requirements in the current FDA Food Code would

be tremendously more successful in protecting the public's health than the "Pathogen Reduction and Hazard Analysis and Critical Control Points Systems" plan.

SUMMARY AND RECOMMENDATION

There are many factors that are associated with bacterial contamination of a carcass. Handling practices during the slaughter-dressing procedures, general sanitation of the plant, specific environmental contaminants at certain locations within a plant, and the origin and cleanliness of the animals undergoing slaughter are all variables that contribute to contamination on a carcass. It has been repeatedly demonstrated that microorganisms are not evenly distributed from carcass to carcass, nor are they evenly distributed over the surface of a single carcass.

The number of cattle slaughtered among the 6,200 plants which will be affected by this new policy varies from less than 10 head per day to more than 5,000 head per day. The number of animals that are slaughtered within a specific plant fluctuates from day to day and has seasonal variability, depending on the market, holidays, etc. Plants will not be required to conduct microbial testing of every carcass, and a sampling plan with an equitable sampling frequency to determine how many carcasses shall be tested within each of the various plants has not been established. As a result, the uncertain number of carcasses to be sampled, and the undetermined morphological location that should be sampled on specific carcasses, makes this "Pathogen Reduction and Hazard Analysis and Critical Control Points Systems" plan for the meat industry far too variable to provide effective protection to the general public.

The prolonged implementation schedule that is planned for this mandate is certain to have negative consequences. FSIS originally proposed to phase in implementation of HACCP during a 12 to 36-month period primarily on a process-by-process basis, but the revised implementation schedule will be based on the size of the establishment, rather than on a process-by-process basis. The HACCP regulations set forth in the final rule will be effective as follows:

1. In large establishments, those with more than 500 employees, the effective date will be 18 months after publication of the final rule.

2. In smaller establishments, those with 500 or fewer but 10 or more employees, the effective date will be 30 months after publication of the final rule.

3. In very small establishments, those having fewer than 10 employees or annual sales of less than $2.5 million, the effective date will be 42 months after publication of the final rule.

The rule has been developed to minimize the economic impact on small and very small plants. Small plants are those with 500 or fewer employees, the Small Business Administration's size standard for small meat and poultry manufacturing establishments. In addition, FSIS has designated establishments "very small" if they have fewer than 10 employees or annual sales of less than $2.5 million.

FSIS is allowing small and very small federal and state plants additional time to meet the new HACCP requirement and the *Salmonella* performance standard, thus minimizing the economic burden. Small plants have 30 months to implement HACCP systems and meet

pathogen reduction performance standards and very small plants have 42 months. All plants, regardless of size, will implement sanitation standard operating procedures and *E. coli* testing requirements at the same time, six months after publication of the final rule. Plants that now have good processing controls are expected to have relatively few implementation costs to comply with the proposal. Plants with little or no process controls would need to invest more to comply.

The variation with this schedule allows small and very small plants to operate for 30 and 42 months respectively without implementing the HACCP system and pathogen reduction performance standards while the large plants are required to comply within 18 months. This provides a definite economical advantage for smaller plants over the large plants. Of the 6,200 USDA-inspected slaughter, processing, and combination slaughter and processing plants, over 2,900 are considered small plants and another 2,900 are considered very small plants.

The *Salmonella* pathogen reduction performance standards regulations will be effective simultaneously with the effective dates for implementation of HACCP as set forth above. Both the Sanitation SOPs and the *E. coli* process control testing regulations will be effective 6 months after publication of the final rule for all plants, regardless of size.

Over a four-year period, the estimated cost to the meat and poultry industry for developing, implementing and operating the proposed pathogen reduction and HACCP systems is estimated at $305 to $357 million, averaging $76 to $89 million per year. The recurring cost after full implementation of the pathogen reduction and HACCP systems is

estimated at $99.6 to $119.8 million per year. It should be pointed out that these are the USDA estimates, and industry strongly disagrees, believing the costs to be much higher.

The meat industry is a complex system of exchange similar to the stock market. Primals are bought, sold, and traded based on a daily national price that determines the value. When portions of the industry are regulated differently than other portions (e.g. large plants incurring implementation costs before smaller plants) the cost of meat will not be the same from all segments of the industry. Although the impact at this time is uncertain, there will undoubtedly be an impact on the market.

The Presidential mandate requires culturing of *Salmonella* and *E. coli* at origin, or at the slaughter/processing plant. It is based on the primary risk factor for infection with *E. coli* 0157:H7 identified prior to 1994, which was ground beef, and on the CDC reports listing *Salmonella* as the most commonly reported cause of foodborne illness in the United States. Even if ground beef was still the number one risk factor, (and it appears that is no longer true), it should be noted that much of the ground beef that is sold and consumed in the United States doesn't originate from the slaughter/processing plant. Ground beef is commonly produced at the retail level by grocery markets and retail meat markets. There are currently 2,965 facilities in the U.S. that grind meat, of which less than 900 slaughter cattle. Most retailers produce ground beef using purchased beef products, then grind there own beef into hamburger and hamburger patties. In 1992, there were 30,700 supermarkets with in-house meat departments (37). The ingredients for most of the ground beef are unused trimmings from primals that are processed into retail cuts, or retail cuts that didn't sell right away and

have undergone a slight color change. Determining an accurate level of contamination with *E. coli* from routine culturing of a few sample carcasses at origin is impossible, unless the entire surface of every the carcass was evenly contaminated. In the final analysis, meat that is used for grinding into ground beef is less likely to have been sampled at the plant, more likely to have undergone excessive handling, and more likely to have experienced temperature abuse. All of these factors increase the likelihood of contamination beyond the plant and decrease the effectiveness of a program whose target is at origin.

Likewise, using *Salmonella* as a basis for justifying the microbial testing in beef and poultry is a misdirected requirement. A detailed analysis of the CDC Surveillance Summaries plainly reveals that, *Salmonella enteritidis* was the most commonly reported cause of foodborne disease in the U.S. during the 5 year period from 1988-92, but most of the outbreaks with a known vehicle were associated with eggs or products containing eggs, and a very small percentage was associated with beef and poultry. This observation is evident for each of the 5 years reported and is demonstrated in Table 6.

Table 6: CDC Surveillance Summaries For *Salmonella enteritidis*

YEAR	% OUTBREAKS FROM EGGS / EGG PRODUCTS	% OUTBREAKS FROM BEEF AND POULTRY
1988	64	15
1989	62	9
1990	68	12.5
1991	50	12.3
1992	88	0

The difference in these figures is so obvious that a statistical analysis is not necessary. These factors demonstrate how microbial testing for *Salmonella* and *E. coli* as required in the mandated "Pathogen Reduction and Hazard Analysis and Critical Control Points Systems" plan for meat plants cannot provide for a safer meat supply.

The FDA Food Code lists safeguards for protecting the public, but the Code is a Federal document with no authority unless it is adopted and enforced by the states. Currently only 7 states or municipalities within the state, the USAF, and the US Army Veterinary Command have adopted and implemented portions of the Code, leaving 43 states still debating, and operating under outdated regulations. The reasons the 1995 Food Code has not been readily accepted and adopted are:

1. Volume: the Food Code contains over 460 pages. Only 168 of those pages are regulatory, with the rest of the document being supplemental information designed to help the foodservice industry and the regulatory officials to understand the requirements.

2. Politics: officials from the various State Health Departments and the FDA are members of national associations (e.g. National Conference for Food Protection, International Association of Milk, Food and Environmental Sanitarians, others) but are outnumbered. People from the food service industry comprise the majority membership of these associations. At the national meetings, the industry personnel yield an overwhelming lobby of opposition to the adoption of the new Food Code.

Ironically, many of the obstacles in adopting the Code are issues other than the protection of the public's health, such as required equipment, management responsibilities, and posting of consumer warnings for undercooked items. When milk was recognized as a vehicle for pathogenic organisms, no thought was given to culturing the milk at origin to determine its safety. Such requirements would have been far too costly and more importantly, would not be effective against all the possible diseases that could be transmitted in raw milk. With the recognition of raw meat as a risk factor for pathogenic organisms, this same common sense approach has been cast aside, yielding to the political ploys which give the appearance of using sophisticated and modern science to ensure food safety. In reality, safe food can never be assured by regulatory requirements at origin. This was recognized and conceded by the writers of the President's radio address and again by FSIS officials writing the final rule:

1. (QUOTE from final paragraph of the July 6, 1996 radio address, pg. 4, this manuscript). To be sure, parents will also still have to take responsibility. There is no way to make food entirely free from risk, nature simply won't let us. So everyone should follow warning labels, be careful how you handle raw meat and poultry, and make sure it's well cooked before you serve it to your family.

2. (From final paragraph of Safe Handling Beyond The Plant, pg. 22, this manuscript). Even as progress is made in reducing contamination during these stages, it will remain critical that retail food handlers and consumers follow safe food handling practices. Proper storage, preparation, and cooking of meat products are essential to

achieving the goal of reducing the risk of foodborne illness to the maximum extent possible.

Failure by the states to adopt the Food Code is obstructing public health regulations that would go far in protecting the American public from infections caused by *E. coli* 0157:H7 as well as gastrointestinal illness caused by other bacterial and viral agents. It would be much more effective than the 1996 President's mandated "Pathogen Reduction and Hazard Analysis and Critical Control Points Systems" plan. While the HACCP and SSOP requirements of the mandate are sound principles, the microbiological testing requirement is not, because it addresses only the first line of defense, ignoring the potential for microbial contamination and growth beyond the plant. Additionally, the microbial testing requirement is an example of the proverbial "bark with no bite". In describing the *E. coli* testing, the final rule states "FSIS will not use the test results by themselves to take any regulatory action but will consider them in conjunction with other information to evaluate whether a problem exists that requires regulatory action". If testing will not result in regulatory action, why impose the expense associated with the requirement? Perhaps FSIS realizes the ineffectiveness of the microbiological test requirement, and is only imposing that portion of the program as a smokescreen. One that will be considered politically responsive to the misinformed lobbyists and media personnel who have been leading the call to "do something", however meaningless it may be.

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VITA

Danny Joe Glover was born in Marlow, Oklahoma, on February 21, 1953, the last of five children born to Ster Phil and Ella Catherine Glover. After graduation from Marlow High School in 1971, he attended Murray State College, at Tishomingo, Oklahoma, where he attained an Associate of Science degree in pre-veterinary science. In the fall of 1973, he transferred to Oklahoma State University, in Stillwater, Oklahoma, and completed a Bachelor of Arts degree. He was accepted into the College of Veterinary Medicine at Oklahoma State University and began his veterinary studies in August 1975. Following graduation from the College of Veterinary Medicine in 1979, he entered private practice in Milan, Tennessee. In 1980, he moved back to Oklahoma, where he remained in private practice until September 1988, when he entered the United States Air Force. He has served in the USAF until the present, and is a career Public Health Officer. He married Risa R. Merideth in 1977 and they have two children, Ashley Renea born in 1979, and Daniel Aaron born in 1981.

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